

REMARKS

The office action of November 22, 2004 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested.

Examiner Interview

Examiner Brown is thanked for the courtesies extended to the undersigned during an interview on February 14, 2005. During the interview, differences were discussed between the prior art of record and the female condom and method recited in the pending claims. As reflected by the Examiner's allowance of method claims 31 and 32, the Examiner recognizes that the tensegrity principles of the present invention are not taught or suggested by the prior art of record. As reflected in the Interview Summary, it was agreed that structural features directed to the tensegrity principles in independent product (condom) claims 1 and 33 would be favorably considered, including the structural feature of a portion of a condom tented against the introitus in the general shape of an hour-glass. Accordingly, claims 1 and 33 have been amended to recite that the proximal pouch portion tents against the introitus in the general shape of an hour-glass.

As further reflected in the Interview Summary, it was also agreed that U.S. Patent No. 4,805,604 to Sperry does not teach an assembly for preplacing a female condom within a vaginal canal in which the condom is enclosed within the assembly. Accordingly, independent claim 36 has been amended to clarify that the condom is enclosed within the assembly prior to insertion.

Allowable subject matter

Applicants thank the examiner for the indication that claims 18-21 and 29 would be allowable if rewritten in independent form. In view of the allowability of base claim 1, as discussed below, these claims have been maintained in their original dependent form.

In addition, Applicants appreciate the examiner's allowance of claims 31-32. Claims 41-42, which presently stand rejected under 35 U.S.C. 103(a) over U.S. Patent No. 6,569,083 to Kassman ("Kassman") in view of applicant provided prior art, have been amended to depend

from claim 31. Thus, it is respectfully submitted that claims 41 and 42 are *prima facie* allowable along with claim 31.

Rejections based on U.S. Patent No. 6,569,083 to Kassman ("Kassman")

Claims 1, 4-5, 9, 13-15, 17, 22, 26, 30 and 33 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Kassman. Claims 2-3, 6-8, 10-12, 16, 22-25, 27-28, and 41-42 stand rejected as allegedly being unpatentable over Kassman in view of either applicant provided prior art or other cited secondary references. Applicants have addressed above the allowability of claims 41 and 42. Applicants respectfully request reconsideration and withdrawal of the remaining rejections as well, especially in view of the present claim amendments.

Independent claim 33 is directed to a female condom, *in situ*, i.e., retained with a vaginal canal of a woman. The condom has a tubular pouch, an external biasing member, an internal biasing member, and a proximal portion of the tubular pouch between an open end of the pouch and the internal biasing member. As amended, claim 33 recites the structural feature of the proximal portion tenting against the introitus in the general shape of an hour glass. Similarly, independent claim 1 recites a female condom configured such that when the condom is installed within a woman's vagina, a proximal portion is tented against the introitus in the general shape of an hour-glass.

Claim 33, directed to a female condom *in situ*, clearly recites the tensegrity related structure that the Examiner has acknowledged patentably distinguishes over the prior art. The recitations of claim 1 are equally distinguishing. The case of *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976) is instructive in this regard. Therein, the Court of Customs and Patent Appeals held that language reciting attributes of components of a kit intended to be assembled, in terms of their configuration when assembled, are proper as present structural limitations of the claimed invention. Such structural limitations must be given weight in making the patentability determination.

The invention at issue in *In re Venezia* was a splice connector kit having unassembled parts that can be assembled and used to make a splice. The claims at issue in *Venezia* recited parts "capable of being assembled" and "adapted to be positioned" in certain configurations

when assembled and used to splice cable. The Court held, “the claimed invention does include *present structural limitations* on each part, which structural limitations are defined by how the parts are to be interconnected in the final assembly, if assembled” (emphasis added). *Id.* at 151. The Court pointed out that “claim 31 calls for ‘a pair of sleeves *** each sleeve of said pair *adapted to be fitted* over the insulating jacket of one of said cables.’ Rather than being a mere direction of activities to take place in the future, *this language imparts a structural limitation* to the [claimed] sleeve” (2d emphasis added). *Id.* at 151-52. Similarly, the recitation in claim 1 of a tenting configuration “in the general shape of an hour glass,” that exists when the condom is installed within a woman’s vagina, imparts a patentably distinguishing structural limitation.

As agreed in the interview, the prior art of record does not teach or suggest a condom with a proximal portion which, in use, tents against a user’s introitus in the general shape of an hour-glass. In contrast, Kassman discloses a female condom having inflatable microtubules extending longitudinally along a tube that, when inflated, provide a stiffening effect to hold the tube in a desired shape during use and to press against the vaginal wall. The Kassman tube has an “increasing diameter as one progresses from the end of the region 80 nearest the closed end 83 of the condom 76 to the open end 82.” Col. 17, lines 58-61. “The outward sloping member 78 is designed to more closely conform the condom 76 to the vestibule of the vagina and the pudendal cleft outside the vaginal orifice after the microtubules in the condom 76 are inflated than would be possible with a conventional condom of constant diametrical dimension.” Col. 17, lines 61-66. Thus, Kassman discloses a female condom having a tube of increasing diameter along its length, which, during use, becomes a stiffened tube.

Clearly, Kassman does not teach tenting of any portion of its condom against a woman’s introitus during use, nor does it teach doing so in the general shape of an hour-glass, as recited in independent claims 1 and 33. In addition, the prior art of applicants’ Figure 1 and the other cited secondary references do not overcome these deficiencies of Kassman. Accordingly, Applicants respectfully submit that independent claim 1, claims 2-29 depending therefrom, and independent claim 33, are allowable over Kassman, either alone or in combination with the cited secondary references.

Rejections based on U.S. Patent No. 5,433,219 to Sperry ("Sperry")

Claims 36-39 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Sperry, and claim 40 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sperry in view of Kassman. Applicants respectfully request reconsideration and withdrawal of these rejections.

Independent claim 36, as amended, recites an assembly comprising an inserter device and a female condom *enclosed* within the inserter device. As agreed to in the interview, this subject matter is not taught or suggested by the prior art of record.

In contrast, Sperry discloses a female condom insertion assembly having a portion of the condom disposed outside of the insertion assembly. As shown in Fig. 2 of Sperry, a closed-end 1(a) of the condom body is placed into insertion tube 4, and a rear portion 1(b) "*extends outside* the front portion 4(a) of the insertion tube 4, and is rolled up around the rings 2 and 3." Emphasis added. Col. 3, lines 62-64.

Thus, Sperry does not teach a female condom enclosed with an inserter device, as recited in independent claim 36. Kassman does not overcome this deficiency of Sperry. Accordingly, Applicants respectfully submit that independent claim 36, and claims 37-40 depending therefrom, are allowable over Sperry, either alone or in combination with Kassman.

Application. No.: 09/921,016
Amendment dated March 18, 2005
Reply to Office Action of November 22, 2004

Conclusion


Based on the foregoing, Applicants respectfully submit that the application is in condition for allowance and a Notice to that effect is earnestly solicited. Should the Examiner believe that anything further is desirable in order to place the application in even better form for allowance, the Examiner is respectfully urged to contact applicant's undersigned representative at the below-listed number.

Respectfully submitted,

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Dated: March 22, 2005

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